The Viveve System is a Non-Invasive Treatment for Vaginal Introital Laxity that Improve Sexual Function in Adult Female Subjects

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Disclosures

• Dr. Michael L Krychman wishes to disclose the following: He is the Chief Medical Consultant for Viveve Medical, Inc, and chairs the Company’s Medical Advisory Board.

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The Condition, The Problem, and Current Solutions

• Vaginal childbirth permanently stretches vaginal tissue

• Resulting looseness can cause:
  • diminished physical sensation during intercourse
  • reduction of sexual satisfaction
  • change in relationship with her sexual partner

• Infrequently discussed with OB/GYNs
  • physicians have no proven options to offer

• Solutions are lacking
  • Surgery and kegels
Patient Reported Physical Changes After Pregnancy (Physician Perspective)

- Vaginal Laxity or change of physical sensation: 88%
- Weight Gain: 83%
- Urinary Incontinence: 75%
- Loose or Flabby Stomach: 67%
- Stretch Marks: 60%
- Sagging Breasts: 50%
- Fecal Incontinence: 24%
- Other: 8%

Viveve Quantitative Physician Research of 525 US Ob/Gyn physicians, conducted Oct 2009
Treatment Paradigm: Vaginal Laxity

• **Behavioral /Kegel Exercises**
  - Significant patient directed teaching
  - Time consuming, Poor efficacy and compliance
  - Addresses pelvic floor muscles, not introital tissue

• **Viveve Treatment**
  - Non-invasive 30 minute office based procedure
  - Quick and easy recovery
  - Proven safety and efficacy
  - Cost effective

• **Surgical Intervention**
  - Invasive, painful surgical operation
  - Significant recovery period
  - Potential for serious surgical complications
  - May require repeat operation
  - Very costly
The Viveve Non-Surgical Solution

- Patented, proven, reverse-thermal gradient technology
- Radiofrequency ("RF") generator with integrated cooling module
- Hand piece and disposable treatment tip
Treatment Protocol

Think of vaginal opening as face of a clock

- Place treatment tip at 1 o’clock position immediately behind vaginal opening
- Depress foot pedal to delivery 3 phased pulse (cooling/heating/cooling)
- Rotate treatment tip 1 cm clockwise and deliver 3 phased pulse
- Repeat until treatment tip is positioned at 11 o’clock position
- Avoid urethra (11 o’clock to 1 o’clock)
- Reposition treatment tip at 1 o’clock position and repeat process
- Treatment is complete after 5 full passes or ~100 pulses
Procedure Benefits

• Non-surgical

• In-office, 30 minute treatment, can be repeated

• Simple and safe with no anesthesia required

• No downtime
Past
Clinical Support

• Sheep study demonstrated collagen remodeling
  • No evidence of necrosis or scarring
  • Clear evidence of collagen reformation

• First in Women Non-Significant Risk IRB study demonstrated safety and efficacy

• Widely accepted research
  • Six poster presentations (ACOG, AUGS, ISSWSH, ISSM)
  • Three podium presentations (AAGL, ICS/IUGA, SPIE)
  • Journal of Sexual Medicine article (Sept 2010)
  • Journal of Women’s Health (Nov 2013)
Mechanism of Action
First In Woman Study

Subject Self Report — Vaginal Laxity/Tightness Questionnaire (VLQ)

Vaginal Laxity Questionnaire (VLQ), subject’s response category (corresponding numerical code): Very Tight (7), Moderately Tight (6), Slightly Tight (5), Neither Tight nor Loose (4), Slightly Loose (3), Moderately Loose (2), Very Loose (1)

Values are means ± 95% confidence interval (error bars) at each assessment. P values compare. Scores at each assessment relative to score at Pre-treatment (Wilcoxon signed rank test).
First In Woman Study (cont’d)

Subject Self Report—Sexual Satisfaction Questionnaire (SSQ)

Cohort A – 12 patients who reported decrease in sexual satisfaction post birth

Sexual satisfaction: Excellent [5], very good [4], good [3], fair [2], poor [1], none [0]
Present
Present

• Currently available in Hong Kong, Japan, and Canada

• CE mark allows Viveve System sales in Europe; launching into select European countries in early 2015

• Working with FDA to finalize IDE study protocol for U.S.

• To date, over 400 procedures performed without SAEs
Future
VIVEVE I Study
VIveve Treatment of the Vaginal Introitus to EValuate Efficacy

Post-Market, Parallel Group Study Design

Design:

• A prospective, longitudinal, randomized, single-blind, sham controlled clinical study

• Designed to demonstrate that active treatment (i.e., Viveve Procedure) is superior to the sham treatment for the primary effectiveness and safety endpoints.

• The active treatment group will receive a treatment dose of 90 J/cm² and the sham group will receive a sub-therapeutic dose of 1 J/cm².

• Subjects will be seen at one, three, and six months post treatment
VIVEVE I Study

Number of Evaluable Subjects to be Enrolled

• 113 subjects in 2:1 randomization scheme (75 subjects in the active arm and 38 subjects in the sham arm)

Clinical Sites

• Up to ten (10) clinical sites

Study Population

• Pre-menopausal females 18 years of age or older who have experienced at least one full term vaginal delivery (>36 completed weeks gestation) at least 12 months prior to enrollment date.
VIVEVE I Study

Primary Effectiveness Endpoint

• The proportion of subjects in the active arm as compared to the proportion of the subjects in the sham arm reporting no vaginal laxity at six months post-intervention
• “No vaginal laxity” is operationally defined as a score > 4 on the VSQ, a patient reported global assessment of vaginal laxity

Primary Safety Endpoint

• The proportion of subjects in the active arm experiencing an AE by six months post-treatment as compared to the proportion of the subjects in the sham arm experiencing an AE by six months post-intervention.
VIVEVE I Study

Secondary Effectiveness Endpoints

• The percent change in Vaginal Introitus Laxity Inventory (VALI) mean score from baseline to six months post-intervention in the active arm compared to the percent change in the Vaginal Introitus Laxity Inventory (VALI) mean score from baseline to six months post-intervention in the sham arm.

• The percent change in Total FSFI mean score from baseline to six months post-intervention in the active arm in contrast to the percent change in Total FSFI mean score from baseline to six months post-intervention in the sham arm.

• The percent change in Female Sexual Distress Scale-Revised (FSDS-R) mean score from baseline to six months post-intervention in the active arm in contrast to the percent change in FSDS-R mean score from baseline to six months post-intervention in the sham arm.
Thank you for your kind attention

Questions and Answers